UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,933	02/17/2004	Satishkumar Ambalal Patel	G-33655P1	9351

1095 7590 07/03/2006

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/779,933	PATEL ET AL.	
	Examiner	Art Unit	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2/2/04 ; 5/17/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Information Disclosure Statements filed on 17 February 2004 and 17 May 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether applicant is claiming triethyl citrate and glycerol monostearate together or in the alternative. Appropriate action is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 and 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanberk, et. al. (EP 0 519 114 A1) in view of Glad, et. al. (U.S. Application No. 2004/0101565 A1).

Tanberk, et. al. teach an enterically coated oral dosage pharmaceutical formulation comprising the gastric proton pump inhibitor omeprazole (*see* pg. 2, lines 24-37).

The disclosed composition comprises enterically coated pellets of about 1mm in diameter (*see* page 2, line 44). A disclosed lubricant is sodium lauryl sulphate (*see* page 3, line 2). A disclosed plasticizer is glycerol monostearate (*see* page 3, line 22).

Tanberk, et. al. explain that the enterically coated form of omeprazole has the beneficial effect of protecting the formulation from gastric acid juice (*see* page 2, lines 24-29).

The Tanberk, et. al. reference differs from the instant case in that it does not disclose use of the particular gastric proton pump inhibitor recited, i.e. lansoprazole; nor does the Tanberk, et. al. reference disclose the particular lubricant (magnesium stearate) and plasticizer (glycerol monostearate) recited.

Glad, et. al. teach a pharmaceutical formulation comprising microparticles of gastric proton pump inhibitors, including lansoprazole (*see* paragraphs 0001 and 0018), for the treatment of gastric disorders (*see* paragraph 0081).

The disclosed composition comprises enterically coated microparticles with at least 80% by weight of lansoprazole (*see* paragraph 0012). No intermediate layer exists between the enteric coating and the lansoprazole particles (*see* paragraph 0071). Disclosed lubricants include, *inter alia*, magnesium stearate (*see* paragraph 0068). Disclosed plasticizers include, *inter alia*, glycerol monostearate (*see* paragraph 0068).

Glad, et. al. explain that combining the disclosed agents into a microparticle formulation is beneficial because, "[t]he small size of the microparticles assures a fast and predictable emptying from the stomach and controllable plasma levels of the absorbed drug. From a technological point of view, microparticles are more suitable for

coating and handling since a technical fault during the process is fatal for single unit formulations but less so for multiple unit formulations comprising micropellets. Also, microparticle formulations are more versatile for use in different dosage strengths." *See* paragraph 0003.

While Glad, et. al. do not explicitly teach all the instant claimed percentages and ratios, it is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine a gastric proton pump inhibitor (such as lansoprazole), magnesium stearate and glycerol monostearate into an enterically coated microtablet formulation of 1mm in diameter, as taught by Tanberk, et. al in view of Glad, et. al. Motivation to form said microtablet, as explained by Glad, et. al. would come from the ability to control plasma levels of absorbed drug.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanberk, et. al. (EP 0 519 114 A1) in view Castan, et. al. (U.S. Application No. 2005/0196459 A1) further in view of Glad, et. al. (U.S. Application No. 2004/0101565 A1).

Tanberk, et. al. teach an enterically coated oral dosage pharmaceutical formulation comprising the gastric proton pump inhibitor omeprazole (*see* above). Glad, et. al. teach a pharmaceutical formulation comprising microparticles of gastric proton pump inhibitors, including lansoprazole (*see* above).

The Tanberk, et. al. and Glad, et. al. references differ from the instant case in that they do not disclose an enteric coating of poly(methacrylic acid, ethyl acrylate).

Castan, et. al. teach an oral dosage microparticulate system with delayed and controlled release of active agent (*see* paragraph 0001).

The disclosed microparticulate system may comprise, *inter alia*, lansoprazole (*see* paragraphs 0225 and 0244). The enteric coating disclosed for the microparticles includes, *inter alia*, poly(methacrylic acid, ethyl acrylate) (*see* Examples 2, 5-7 and 9-16).

Castan, et. al. explain that the disclosed enteric coating is beneficial in controlling release of the active agent by pH dependent delayed release (*see* paragraph 0014).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine a gastric proton pump inhibitor (such as lansoprazole), magnesium stearate and glycerol monostearate into a microtablet formulation of 1mm in diameter, as taught by Tanberk, et. al in view of Glad, et. al. and coat the microtablet

with poly(methacrylic acid, ethyl acrylate), as taught by Castan, et. al. Motivation coat the formulation with poly(methacrylic acid, ethyl acrylate), as explained by Castan, et. al., would come from the ability to control the release of active agent.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

***

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600